Op-Ed

Treatment of substance misuse in the new century

Physicians must confront the recurring attitudes of moralism and criminalization

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Services for people who are substance misusers have been greatly reduced under managed care. As newcomers to insurance coverage, they suffer from being "last in, first out." For example, between 1988 and 1998, benefit expenditures for addiction treatment fell by 74.5%, while benefit expenditures for general health fell by 11.5% (The Hay Group: "Substance Abuse Benefit Cost Trends, 1988-1998," unpublished report commissioned by the American Society of Addiction Medicine, Chevy Chase, MD, 1999). Unlike the public outcry against the practice of discharging women 23 hours after childbirth and "drive-by" mastectomies, few voices were raised on behalf of substance misusers. Many rehabilitation facilities closed. Edgehill, one such facility in Newport, Rhode Island, had a program that, despite measuring its success in peer-reviewed studies, was unable to sustain itself with insurance coverage. The publicly funded treatment system for substance misuse, supported by state and federal money (and, therefore, at the mercy of annual legislative budgets), was established in the 1960s and 1970s to serve the poor, the uninsured, and those in jails and prisons. It has also suffered as patients who were formerly insured crowd its caseloads and Medicaid programs are increasingly shifted to managed care. Most substance misusers go without treatment, and others fail to recover in response to inadequate care.[1]

Instead of providing needed services, jurisdictions around the country have begun to prosecute and imprison pregnant and postpartum drug misusers for "prenatal child abuse" and "delivery of controlled substances to a minor" (by the umbilical cord).[2] Few jails and prisons have anything positive to offer these women. Instead, the fear of prosecution acts as a powerful deterrent, keeping substance misusers who are pregnant from both the prenatal care and treatment of their dependency that they so desperately need.

American society has always had a deep ambivalence toward substance misusers. Benjamin Rush, 200 years ago, fostered enlightened understanding and medical treatment of the disease of "inebriety," as alcohol dependence was then known.[3] His ideas were accepted by some, and several treatments of dependency (for example, the "Keeley cure"[4]) were popular in the United States during the 19th century. A self-help movement, known as the Washingtonians and devoted to the "reclamation of drunkards," was also active. Although the movement died out, two of its treatment centers, known as Washingtonian Homes, were still active in 1900.[4]

At the same time, American society regarded substance misusers as morally corrupt. During the 19th century, a growing social movement dictated a radical cure for the nation's alcohol problem—prohibition. The passage of the Eighteenth Amendment in 1919 was meant to eliminate alcohol dependence; therefore, its treatment was thought to be unnecessary. Even after the amendment was repealed, delirium tremens and the complications of alcohol misuse received somewhat reluctant medical attention, and alcohol dependence was considered untreatable. Throughout the first half of the 20th century, it was not unusual for general hospitals to contain language in their bylaws that excluded patients with alcohol dependence. Prohibition left another legacy. Because of the stigma associated with illegal substances, research lagged seriously, a situation that has taken the rest of the century to correct.

America has been similarly ambivalent about the misuse of drugs. In the early 1900s, physicians prescribed morphine to outpatients who were dependent on opiates in an attempt to effect gradual withdrawal or, in some cases, de facto maintenance. However, the Harrison Anti-Narcotic Act of 1914 and its vigorous enforcement against physicians who tried to help substance misusers effectively ended outpatient treatment.[4] What had been a stigmatized condition but still subject to medical intervention was now a crime.

Public and medical attitudes toward addiction began to shift when Alcoholics Anonymous (AA), born in 1935, showed that alcohol misusers could recover. The development of effective treatment units incorporating AA referral and of therapeutic communities for heroin misusers encouraged public acceptance of the disease concept of addiction in the 1970s and 1980s.[5] Methadone treatment, introduced in 1965,[6] became widely accepted, and programs were organized in many states. Encouraged by the apparent success of the new therapies and a growing realization of the social costs of untreated dependency, health insurers began to cover these services, allowing the public sector to concentrate on the uninsured.

The federal government established the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse in the 1970s, greatly advancing research in the area. The term "addiction medicine" was coined in the late 1980s by the American Society of Addiction Medicine and accepted by the American Medical Association as a self-designated specialty. Progress was certainly being made.

Society retained its ambivalence toward drug and alcohol abuse during the 1960s and 1970s. When illicit marijuana, heroin, cocaine, and hallucinogens became widely available and widely used, the nation declared "war on drugs" and began spending billions of dollars on interdiction and prosecution, filling the prisons to overflowing with drug offenders. In the 1980s and 1990s, treatment has once again fallen by the wayside.

In the coming century, physicians' task is to confront these recurring attitudes of moralism and criminalization. Physicians need to assure equitable insurance coverage for substance misuse and to redirect the resources of the war on drugs from reducing supply to reducing demand. Organized medicine must continue to speak for the right of those suffering from the disorders of substance misuse to receive treatment, while promoting research to expand treatment options. Primary care physicians owe it to their patients to improve their skills in the prevention and diagnosis of drug and alcohol problems, including addiction to nicotine. Well-researched techniques are available for screening and brief interventions for the not-yet-dependent misuser, as well as referral and treatment of those who are substance dependent.[7,8] Medical professionals must be heard in the halls of government and by patients in their offices and clinics, lest the progress made in the last century is lost and the nation returns to the hopelessness of the past.

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Congress and the Pain Relief Promotion Act

Will physicians be too scared to prescribe sufficient opioids to patients in pain?

Chilling repercussions are likely to result from the Pain Relief Promotion Act of 1999, a bill (HR2260) passed by the House of Representatives and now being considered by the Senate (S1272; available at: http://thomas.loc.gov). In essence, it is a simple piece of legislation with two major provisions. The first essentially nullifies patients' rights to physician-assisted suicide under the Oregon Death With Dignity Act.[1] It does this by declaring that assisted suicide and euthanasia are not legitimate medical uses of federally controlled drugs and that practitioners who prescribe for these uses are subject to the criminal penalties of the 1970 Controlled Substance Act. The second recognizes the concept of "double effect"—that is, allowing actions with unintended adverse outcomes, if that action is the only way to bring about a more desirable outcome. The application here is the unintended (but acceptable) hastening of death through the use of pain medication, if that is the only way to relieve the suffering of a dying patient.

Ironically, the drafters of this legislation have themselves used double-effect reasoning in this measure. To stifle the actions of a single state, they risk denying pain relief to patients throughout the nation. When physicians realize that this law means that the US Drug Enforcement Agency and federal prosecutors will be judging their "intent" in prescribing, they are likely to back away from aggressive pain relief with opioid analgesics. Supporters of the legislation say that this will not happen, but knowledgeable witnesses speaking before congressional committees have testified otherwise.

This is not the first time that the US Congress has tried to stop Oregon's law. After a second referendum approved physician-assisted suicide by an even larger margin (60%-40%) than the first (51%-49%),[2] the Lethal Drug Abuse Prevention Act of 1998 (HR4006 in the House and S2151 in the Senate) was introduced in the 105th Congress. This proposed legislation would have permitted the revocation of Drug Enforcement Agency registration of physicians or pharmacists who had intentionally dispensed or distributed a controlled substance for the purpose of physician-assisted suicide. Because of opposition, this approach was abandoned and replaced in 1999 with the current bills.

The language of these bills, recognizing double effect and affirming the goals of palliative care (including modest

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program funding), has improved the prospect of their passage over last year's bill. The Pain Relief Promotion Act of 1999 has garnered the support of the American Medical Association and the National Hospice Organization. Some advocates of humane palliative care believe that such legislation would further these goals.

Many others, however, are frightened by the prospect of the federal government second guessing physicians' intent when prescribing controlled substances. This proposed act provides for a criminal penalty against physicians: a maximum of 20 years in jail and license revocation. David Orentlicher, formerly director of the American Medical Association's Division of Medical Ethics, told the House Judiciary Committee: "Given the seriously disruptive and traumatic nature of criminal prosecutions, this act will make physicians err even more on the side of caution."[3] He concluded, "No matter how many words you attempt to write into this act to define and encourage good pain management and palliative care, the reality of the practice of medicine all over the country is that doctors would rather avoid risk, interrogation, and investigation at all costs."

In describing the effect of legal sanctions on physician behavior, Sandra H. Johnson, past president of the American Society of Law, Medicine, and Ethics, wrote,[4]

> Doctors' fears of disciplinary action and criminal prosecution are justified. There is no evidence that large numbers of physicians are sanctioned for their treatment of patients in pain, but the impact of the process on those physicians who are only investigated, or only charged but not disciplined, or only warned or cautioned but not penalized is severe.

Many physicians will think that a large dose of opioid will imply intent to bring about death. Indeed, many physicians are already uncomfortable with the large opioid doses recommended by experts in palliative medicine. One textbook on palliative medicine says, "While doses can become extremely large during this process, the absolute dose is immaterial"[5] as long as the balance between analgesia and side effects remains favorable. A retrospective review of 100 patients at Memorial Sloan-Kettering Cancer Center, New York, in 1990 documented the dosage of opioids in the last days of life. In the 24 hours before death, 23% of the patients required more than 300 mg of intramuscular morphine sulfate (equivalent to 900 mg of oral morphine), and 7% needed more than 2,000 mg of intramuscular morphine (6,000 mg of oral morphine).[6] With the threat of criminal prosecutions looming, how many physicians, fearing such large doses would suggest the intent to kill, would actually follow such recommendations?

If Congress were serious about pain, it would pass Senate bill S941 (House bill HR2188), the Conquering Pain Act, introduced by Senator Ron Wyden of Oregon. This thoughtful and comprehensive bill addresses many of the barriers to adequate pain management and quality care of dying patients, including reimbursement barriers. The bill would establish regional networks to help disseminate information about best practices in pain management. It also calls for surgeon general and Institute of Medicine reports on pain that would include identifying state and federal regulations that pose barriers to care. Unfortunately, the goal of pain relief for millions of Americans is apparently being sacrificed to the desire of this Congress to negate the mandate of the citizens of the state of Oregon.

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Conflict, what conflict?

When trust goes, so does the healing power of physicians

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There is almost nothing more important in the doctor-patient relationship than trust. By trust we mean the knowledge, on the part of patients, that whatever is discussed, whatever information is shared, and whatever advice is offered by the physician, is done so in his or her best interest. Trust in the "fiduciary" behavior of the physician—who will put his or her interest secondary to that of the patient—is one of the basic tenets of professionalism. A profession has unique, defining characteristics, including a group membership to which entry is limited, a special area of knowledge, a position of authority (because of that special knowledge), self-regulation and community

sanction, formal and binding codes of ethics, and a distinctive culture defined by values, norms, and symbols. Along with the status that society grants our (medical) profession, the handsome economic rewards, and patients upon whom we can learn and practice our art, society also bestows on us the autonomy to control and govern ourselves. All this is given in the expectation that we will deserve society's trust, by functioning in the interest of our patients. If we allow self-interest to trump our fiduciary relationship to patients and the community, society has the power to change the rules and take away the enormous privileges it has previously granted.

Such a process is evident regarding the medical profession in the United States today, where the intrusion of economic demands by practice organizations and nonmedical administrators, regulation by non-physicians, threats from the ever-present plaintiff's bar, and even intrusion by legislators into the practice of medicine, threaten to further erode our relationship with patients, but are first and foremost a reflection of an already changing attitude of society towards physicians. Rather than blame others, however, we must look at our own behavior and its impact on this fragile relationship.

Rarely a day goes by without our newspapers reporting on breaches of trust by physicians. The details in each case differ, but they share the same dynamic: a trusted doctor (Dr Koop), healthcare organization (the American Medical Association, or the *New England Journal of Medicine*) or company (Pfizer) is shown to be behaving in a way that is clearly more self-interested than trustworthy. Physicians take "gifts" from drug companies and then spend patients' money to help make the same pharmaceutical industry the most profitable in the world. They recruit "research" subjects without advising them of the personal financial gain that accrues to them. They order more tests when this stands to earn them more money and fewer tests when that does. They take payments for journal "articles" written by ghost/writers paid by proprietary companies, and the commentaries and editorials they themselves write are greatly influenced by their personal and financial relationships to such companies. All these behaviors are directly opposed to what patients and society expect from us in return for the privileges they have bestowed.

Journals need to develop cogent and coherent policies regarding conflicts of interest: in writers, editorialists, reviewers, and editors. The *WJM* would define conflicts of interests as a set of conditions in which professional judgment about one area may be influenced by clear-cut competing interests, such as personal financial gain. We have no doubt that a conflict of interest exists when the *New England Journal of Medicine* publishes drug reviews written by authors who are, or have recently been, in the pay of the pharmaceutical industry.[1] Similarly, it is a conflict of interest when the former surgeon general—a man who has been held out as a beacon of righteousness and probity—runs a for-profit web page that offers advice through messages that are actually paid advertisements, without acknowledging this fact to consumers. Similarly, when the same man criticizes the findings of an expert public body without acknowledging that he is being paid by the industry (latex glove manufacturers)[2] that stands to lose because of the report in question, conflict of interest is clear, and societal trust is threatened.

Does any of this really matter? Isn't it just the American way? And isn't science pure, with its methods transparent, such that motives really don't make a difference to outcomes? So what if scientists receive grant support from a drug company—that won't influence what they write or think. So what if doctors receive boondoggles and cash from drug companies? That won't influence their prescribing practices. What of medical schools that sell their departments or hospitals for a few million in exchange for hanging a company's name over the front door—does that really impact the teaching and patient-care missions? And what of medical journals that are full of drug advertising—this in no way suggests that they will select research papers in such a way as not to offend the hand that feeds them—right? Perhaps the alarms and warnings are just being raised by a bunch of do-gooders who are ranting and raving about morals and righteousness without any evidence of harmful impact.

In fact many of these areas have been carefully studied, with the constant finding that conflicts of interest do make a difference. As pointed out recently in the *BMJ*,[3] the potential for financial gain will lead doctors to refer more patients for tests, operations, research studies, and hospital admissions and it will lead physicians to ask that drugs be placed on a hospital formulary.[4-6] Papers published in sponsored journal "supplements" are inferior in quality to those published in the mother journal.[7] Reviews and commentaries in which the author has a link to a company with a vested interest are more likely to be positive in their conclusions than are those with no such link.[8-10] Authors and researchers feel obligated to sponsoring companies and are concerned about what will happen if their findings are not those desired by the sponsor.[10,11]

Of course conflicts of interest need not be solely financial; they can be political, academic, religious or self-aggrandizing (related to prestige). And conflicts are not the sole domain of authors. Peer reviewers, government officials, and even journal editors can have conflicts of interest. It is impossible to avoid them entirely or to estimate in every case the presence or degree of conflict. Nevertheless we strive to limit clear-cut conflicts of interest wherever possible and to assure transparency, so that readers can evaluate for themselves the possibility of biased results, analysis, or recommendations. To this end, we have chosen to adopt many of the "conflict of interest" guidelines

used by the *BMJ* (see http://www.ewjm.com), and have added some of our own.

- We will not publish papers, articles, or commentaries that are not directly and personally written by the "author" (we will not accept prose that is penned by a company or public relations agency or prose for which the author has been paid by a party with a vested interest).
- We will try not to solicit commentaries from anyone who has what we believe is a clear-cut conflict of interest. In a case for which we suspend this rule, in order to include the thoughts of someone who is clearly a leader in the area of interest, we will let you, the reader, know of the perceived conflict on the first page of text, so you can estimate for yourself its importance.
- Given the hard financial reality of journal publishing we may need to accept advertising. We will however try to focus on advertisers who are selling products to our readers themselves (vacations, books, cars, sports equipment, etc), rather than those marketing products for physicians to use on patients.
- We will ask all authors, including those who send letters to the editor, to sign our conflict of interest statement (see Guidelines for Authors) and divulge any potential conflicts.
- We will be honest with ourselves in acknowledging that conflicts are everywhere—even at a high quality journal such as the *WJM.*

We invite you, our readers, to inform us if there are biases or conflicts that we don't recognize. And we will do our best to listen to you and always strive to do better.

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Functional foods: health boon or quackery?

The FDA must get tough to safeguard consumers' health

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The dividing line between foods and drugs is blurring. Consumers can buy a growing variety of functional foods that claim to help prevent everything from the common cold to cancer. Some of these products are fortified with higher levels of naturally occurring substances, such as calcium, than are normally found in foods. Others contain medicinal herbs, such as echinacea (*Echinacea purpurea* root), Saint John's wort, and kava kava (derived from *Piper methystici rhizoma* which are not approved for food use.

Labels commonly boast that functional foods will increase energy levels, strengthen memory, or provide other benefits. Odwalla, Inc. markets "Serious Energy," a blend of several fruit juices that are "infused with power producing herbs including two forms of ginseng, gotu kola (*Centella asiatica*), green tea extract" and two mushroom derivatives. Neither the ginseng nor the gotu kola is an approved food ingredient. Although green tea itself is "generally recognized as safe" within the meaning of the Federal Food, Drug, and Cosmetic Act, extracts of green tea may not be seen as such. Whether the product offers energy and power beyond the calories from sugars is questionable.

Golden Temple sells "Herbal Brain Power" cereal with ginkgo (derived from the *Ginkgo biloba* tree) and gotu kola to "support mental alertness." Those herbal ingredients are unapproved, and the claim is unsubstantiated. Ben & Jerry's Homemade, Inc. markets a line of frozen smoothies (drinks) that contain such unapproved ingredients as echinacea and ginseng, two herbs with questionable benefits. "Raspberry Renewal," which contains ginseng, is promoted as an "energizer," a claim unsupported by studies. Robert's American Gourmet markets a snack food, Ginkgo Biloba Rings, as a "memory snack." There is no evidence that ginkgo improves memory. So what is our food supply turning into?

In some cases, added ingredients in foods offer real benefits. Decades ago, iodized salt and enriched flour helped prevent deficiency diseases. Today, orange juice fortified with calcium helps strengthen bones, flour en-

riched with folate helps prevent neural tube defects, and grain products fortified with oat bran or psyllium may reduce the risk of heart disease.[1]

But questions and problems arise when the added substances are poorly tested or unsafe, purported benefits are based on flimsy evidence, trivially small or dangerously large amounts of a beneficial substance are used, or foods are deceptively labeled. To date, other than deceiving consumers, functional foods have not caused harm. But it may only be a matter of time before consumers with hypersensitivities suffer serious adverse reactions from functional ingredients or from interactions between a functional ingredient and alcohol or a drug.

Functional foods may provide a major health boon or result in a new generation of quackery

The US Food and Drug Administration (FDA)[2] and state consumer agencies initially allowed companies to ignore or exploit loopholes in the law. Recently, however, the FDA has become more active. In 1998 and 1999, the FDA issued several courtesy letters regarding illegal attempts to market processed foods as dietary supplements to bring the products under weaker safety and labeling laws.[3] These products were Benecol margarine (McNeil Consumer Products Co., a subsidiary of Johnson & Johnson), containing plant stanol esters to promote "healthier lower cholesterol levels"; Kitchen Prescription soup (Hain Food Group) containing echinacea, claimed to "support your immune system," and soup containing Saint John's wort, claimed to "give your mood a natural lift"; and Actimel breakfast drink (Dannon Company) containing three yogurt cultures said to be "clinically proven to help fortify your body's natural defenses."

Ultimately, the plant sterols in Benecol margarine were determined to be "generally recognized as safe," and Hain stopped selling its soups. Dannon maintains that Actimel is a dietary supplement and continues to market the product while it negotiates with the FDA.

In September 1999, the FDA issued to Langer Juice Company what is probably its first warning letter concerning functional foods.[4] The FDA cited three kinds of legal violations. The first was failure to show safety: the company's juices contain ingredients (echinacea, grape seed extract, and *Ginkgo biloba*) that are not "generally recognized as safe" or approved as food additives. The second violation was unapproved health claims: such statements as "protect your heart as you quench your thirst" cannot be used until the FDA has approved their use. The third violation was claims about nutritional content: claims made for flavonoids were inappropriate because they have no established nutritive value. The FDA also told the company that any claimed effects for the functional ingredients must be linked to their nutritive value and not pharmacologic effects. It remains to be seen whether the FDA will invoke its power to seize these products or obtain an injunction to prevent their sale.

Welcome as they are, the FDA's enforcement efforts have been late and spotty. The composition of, and claims for, functional foods should be governed by judicious government regulation, not by corporate marketing strategies. The unbridled marketing of approximately $12 billion worth of dietary supplements annually[5] shows the potential for defrauding and making consumers unwell. Although most supplements are safe and honestly labeled, some are worthless, hazardous, or deceptively labeled.[6]

To prevent the spread of such mischief to the far larger food industry, the FDA and state agencies must be proactive. The FDA must initiate enforcement actions in a timely manner to demonstrate that it is serious about enforcing the laws governing ingredients and labeling claims. Industrywide regulations specifying what can and cannot be said on a label are essential. The Federal Trade Commission must follow the FDA's lead and prohibit the advertising of claims that the FDA would not permit on labels.

Functional foods may provide a major health boon or result in a new generation of quackery. Which outcome prevails will depend on whether government ensures that the foods are safe, nutritious, and honestly labeled.

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